

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS**

RONALD ALANIZ, ) Case No. 21-308  
vs. )  
Plaintiff, )  
vs. )  
C.R. BARD, INC., a New Jersey corporation, )  
BARD PERIPHERAL VASCULAR, INC., )  
(a subsidiary and/or division of defendant C.R. ) **DEMAND FOR A JURY TRIAL**  
BARD, INC.) an Arizona corporation, )  
Defendants. )

**ORIGINAL COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

Plaintiff RONALD ALANIZ, by and through his undersigned attorneys, hereby sue Defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC., (collectively, the “Defendants”) and allege as follows:

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "filter").

## PARTIES

**Plaintiff**

2. Plaintiff, Ronald Alaniz, (hereinafter "Plaintiff" or "Mr. Alaniz") is a citizen of and resident in Rio Grande City, Texas which is located in Starr County, Texas.

3. The C.R. Bard G2® Filter System which gives rise to this cause of action was implanted into Plaintiff's body at Wilford Hall Medical Center in San Antonio, Bexar County, Texas on or around November 26, 2006.

1       4.     Venue is proper in this judicial district as a substantial part of the events or omissions  
2 giving rise to the claim occurred within this judicial district and the Defendants regularly conduct  
3 business in this District.  
4

5       **Defendants**

6       5.    Defendant C. R. Bard, Inc. is a wholly-subsidiary of Becton, Dickinson and Company., and  
7                    is a New Jersey corporation with its principal place of business in New Jersey.  
8       6.    Defendant Bard Peripheral Vascular, Inc. is a wholly-subsidiary of C.R. Bard, Inc., and is an  
9                    Arizona corporation with its principal place of business in Arizona.  
10

11                   **JURISDICTION AND VENUE**

12       7.     Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the plaintiff and  
13 the defendants are citizens of different states, and the amount in controversy exceeds \$75,000, excluding  
14 interest and costs.  
15

16       8.     Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events  
17 or omissions giving rise to the claim occurred within this judicial district and the Defendants regularly  
18 conduct business in this District.  
19

20                   **GENERAL FACTUAL ALLEGATIONS**

21       9.     Plaintiff brings this case for serious injuries suffered by Mr. Alaniz as a result of a  
22 surgically implanted medical device, known as Bard G2® Filter System including but not limited to,  
23 migration and embedment of the filter, device being irretrievable and fracture causing serious illness and  
24 ongoing physical, emotional, and economic damages.  
25

26       10.    The Bard G2® Filter was designed, manufactured, prepared, compounded, assembled,  
27 processed, labeled, marketed, distributed, and sold by Defendants for prevention of blood clots  
28 (thrombi) from traveling from the lower portions of the body to the heart and lungs.  
29

1       11. At all times relevant to this action and prior to Plaintiff Ronald Alaniz, being implanted  
2 with a Bard G2® Filter, Defendants misrepresented the safety of the Bard G2® Filter and negligently  
3 designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed  
4 and sold the Bard G2® Filter as a safe and effective device to be surgically implanted to prevent blood  
5 clots from travelling from the lower portions of the body to the heart and lungs.

6  
7       12. At all times relevant to this action and prior to Plaintiff Ronald Alaniz being implanted  
8 with a Bard G2® Filter, Defendants knew and had reason to know that the Bard G2® Filter was not safe  
9 for the patients for whom they were prescribed and implanted because once implanted the devices were  
10 prone to fracturing, migrating, perforation the inferior vena cava wall and otherwise malfunctioning.

11  
12       13. At all times relevant to this action and prior to Plaintiff Ronald Alaniz being implanted  
13 with an Bard G2® Filter, the Defendants knew and had reason to know that patient implanted with an  
14 Bard G2® Filter had an increased risk of suffering life threatening injuries, including but not limited to:  
15 death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to  
16 myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and  
17 inability to remove the device.

18  
19       14. At all times relevant to this action and prior to Plaintiff Ronald Alaniz being implanted  
20 with a Bard G2® Filter, the Defendants and had reason to know the Bard G2® Filters contained  
21 conditions, which Defendants did not intend, which resulted in the devices not performing as safely as  
22 the ordinary customer would expect.

23  
24       15. Despite having knowledge of the dangers presented by the Bard G2® Filter, the  
25 Defendants failed to adequately warn Plaintiff's health care providers and/or the public at large of these  
26 dangers.

27  
28       **INFERIOR VENA CAVA FILTERS GENERALLY**

1       16.    Inferior Vena Cava (IVC) Filters first came on the medical market in the 1960's. Over  
2 the years, several different medical device manufacturers have introduced several different designs of  
3 IVC filters.

4       17.    An IVC filter is a device that is designed to filter or "catch" blood clots (called  
5 "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be  
6 designed to be implanted, either permanently or temporarily, in the human body, more specifically,  
7 within the inferior vena cava.

8       18.    The inferior vena cava is a vein that returns blood to the heart from the lower portions of  
9 the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis,  
10 through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins.  
11 These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are  
12 considered "pulmonary emboli" or "PE".

13       19.    Certain people are at increased risk for the development of DVT or PE. For instance,  
14 someone who undergoes knee or hip joint replacement is at risk for developing DVT/PE. Obese patients  
15 are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have  
16 experienced previous strokes. A number of other conditions predispose people to develop DVT/PE.

17       20.    Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For  
18 example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting  
19 factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their  
20 conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent  
21 pulmonary thromboembolic events.

22       21.    As stated in this Complaint, IVC filters have been on the market for decades. The first  
23 IVC filters were permanent filters. These devices were designed to be left in a patients IVC permanently

1 and have long term follow-up data (of up to 20 years and longer) supporting their use and efficacy.  
 2 Beginning in 2003, manufactures also began marketing what are known as optional or retrievable filters.  
 3 These filters are designed so that they can be surgically removed from a patient after the risk of PE has  
 4 passed. These IVC filter designs, however, were not intended to remain within the human body for  
 5 indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended  
 6 to remain implanted for a finite period of time. The Recovery Filter, the G2®, G2® Express (also  
 7 known as the G2®X)<sup>1</sup>, Eclipse and Meridian Filter manufactured by Bard and BPV are examples of  
 8 retrievable filters.  
 9

## 10 THE RECOVERY FILTER

11 22. In 2002, Bard and BPV submitted a notification of intent to the FDA to market the  
 12 “Recovery® Filter System” (hereafter “Recovery” or “Recovery Filter”) for the prevention of recurrent  
 13 pulmonary embolism by placement in the inferior vena cava.<sup>2</sup> On November 27, 2002, the FDA cleared  
 14 the Recovery Filter for marketing and use in the prevention of recurrent pulmonary embolism via  
 15 *permanent* placement in the vena cava in the following situations:  
 16  
 17

- 18 a. Pulmonary thromboembolism when anticoagulants are contraindicated;
- 19 b. Failure of anticoagulant therapy for thromboembolic disease;
- 20 c. Emergency treatment following massive pulmonary embolism where anticipated benefits  
     of conventional therapy are reduced;
- 21 d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is  
     contraindicated.

22  
 23 <sup>1</sup> “G2 Filter” – is meant to include the G2 as well as the G2 Express (also known as the G2X) filters manufactured by Bard.  
 24 The only difference between the G2 and the G2 Express is a hook at the top of the device for a physician to attempt removal.

25 <sup>2</sup> Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act (“Act”)  
 26 of 1976 (21 U.S.C. 321 *et seq.*). The 510(k) review process requires any entity engaged in the design, manufacture,  
 27 distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device  
 28 and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81,  
     807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics  
     as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the  
     pre-market approval process.

1       23. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent  
2 to market the Recovery® Filter for the additional intended use of *optional retrieval*. The FDA cleared  
3 this additional intended use on July 25, 2003.

4       24. Bard and BPV began actually marketing the device in April 2003, but did not begin full  
5 market release until 2004. Bard and BPV were aware that the Recovery filter was also used extensively  
6 off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming  
7 surgeries such as bariatric procedures.

8       25. The Recovery Filter consists of two (2) levels of six (6) radially distributed Nitinol struts  
9 that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There  
10 are six short struts, which are commonly referred to as the arms, and six long struts, which are  
11 commonly referred to as the legs. Each strut is held together by a single connection to a cap located at  
12 the top of the device. According to the Patent filed for this device, the short struts are primarily for  
13 “centering” or “positioning” with the vena cava, and the long struts with attached hooks are designed  
14 primarily to prevent the device from migrating in response to “normal respiratory movement” or  
15 “pulmonary embolism.”

16       26. As noted above, the Recovery Filter is constructed with “Nitinol”, which is an acronym  
17 that stands for Nickel Titanium Naval Ordnance Laboratory. “Nitinol” possesses “shape memory.”  
18 Meaning, Nitinol will change shape according to changes in temperature, and then, retake its prior shape  
19 after returning to its initial temperature. When placed in saline, therefore, the Nitinol struts become soft  
20 and can be straightened to allow delivery through a small diameter catheter. The metal struts then  
21 reassume their original shape when warmed to body temperature in the vena cava.

22       27. The Recovery filter is inserted by a catheter that is guided by a physician (normally an  
23 interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery Filter is

1 designed to be retrieved in a similar fashion. The implanting physician normally reviews an imaging  
 2 study prior to placement to determine size of IVC, renal vein location, and to identify any venous  
 3 anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging  
 4 study to confirm successful placement.  
 5

6       28.     The Recovery Filter is prone to an unreasonably high risk of failure and patient injury  
 7 following placement in the human body. Multiple studies have reported Bard's Recovery Filter to have  
 8 a fracture and migration rate ranging from 21% to 31.7%.<sup>3</sup> When such failures occur, shards of the  
 9 device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of  
 10 the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded  
 11 in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These  
 12 patients are exposed to a lifetime of future risk.  
 13

14       29.     The Recovery Filter similarly poses a high risk of perforating the vena cava walls. When  
 15 such failures occur, the device can perforate the duodenum, small bowel, ureter, which may lead to  
 16 retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death.  
 17 Further, given the risks of injury in attempting to remove devices that have perforated the vena cava, the  
 18 device may be irremovable. These patients are faced with a lifetime of future risk.  
 19

20       30.     The Recovery Filter failures described above occur at a substantially higher rate than  
 21 with other IVC filters.  
 22

23       31.     Soon after the Recovery Filter's introduction to the market, Bard and BPV began  
 24 receiving large numbers of adverse event reports from health care providers.  
 25

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26       <sup>3</sup> See e.g., Hull JE, Robertson SW. BARD G2 Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture  
 27 and Migration. *J Vasc Interv Radiol.* 2009;20(1):52-60; Nicholson W, et al. Prevalence of Fracture and Fragment  
 28 Embolization of the BARD G2 and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and  
 Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31.

1       30. The adverse event reports (AERs) associated with IVC filter devices demonstrates that  
 2 Bard's IVC Filters are far more prone to device failure then are other similar devices. A review of the  
 3 FDA MAUDE database from the years 2004-2008 reveals data to establish that Bard's IVC filters are  
 4 responsible for the following percentages of all AERs:

5

- 6       a. 50% of all adverse events
- 7       b. 64% of all occurrences of migration of the device
- 8       c. 69% of all occurrences of vena cava wall perforation
- 9       d. 70% of all occurrences of filter fracture.

10      31. These failures are attributable, in part, to the fact that the Recovery Filter was designed to  
 11 be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

12      32. In addition to design defects, the Recovery Filter suffers from manufacturing defects.  
 13 These manufacturing defects include, but are not limited to, the existence of "draw markings" and  
 14 circumferential grinding markings on the exterior of the surface of the device. The presence of these  
 15 draw markings and/or circumferential grinding markings further compromises the structural integrity of  
 16 the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw  
 17 markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery Filter  
 18 is not of sufficient strength to withstand normal placement within the human body. The presence of the  
 19 aforementioned exterior manufacturing defects makes the device more susceptible to failure.

20      33. Bard and BPV knew that no clinical testing, such as animal studies or simulated use tests,  
 21 was conducted to determine whether the Recovery Filter would perform safely once implanted in the  
 22 human body and subjected normal *in vivo* stresses.

23      34. Soon after the Recovery Filter's introduction to the market in 2003, Bard and BPV began  
 24 receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the  
 25 Recovery® Filter was fracturing post-implantation and that fractured pieces and/or the entire device  
 26 were migrating throughout the human body, including to the heart and lungs. Bard and BPV also

1 received large numbers of AERs reporting that the Recovery Filter was found to have perforated the  
 2 inferior vena cava post-implantation. These failures were often associated with reports of severe patient  
 3 injuries such as:

- 4                   a.     Death;
- 5                   b.     Hemorrhage;
- 6                   c.     Cardiac/pericardial tamponade (pressure caused by a collection of blood in the  
                  area around the heart);
- 7                   d.     Cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 8                   e.     Severe and persistent pain; and
- 9                   f.     Perforations of tissue, vessels and organs.

10                   35.    Within the first year of full market release of the Recovery Filter, Bard and BPV received  
 11 at least 32 AERs reporting that the Recovery Filter had fractured *in vivo* and at least 22 AERs reporting  
 12 that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were  
 13 reported to have been associated with patient death.

14                   36.    From 2003 through September 2005, Bard and BPV received ever growing numbers of  
 15 AERs reporting the above described failures and patient injuries. Defendants knew or should have  
 16 known that the failure rates associated with the Recovery Filter were substantially higher than other  
 17 similar products on the market, yet Bard and BPV failed to warn consumers of this unreasonably  
 18 dangerous device.

19                   37.    In late 2004 or early 2005 Bard and BPV, without notifying consumers of the design and  
 20 manufacturing flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an  
 21 attempt to correct those flaws. The redesigned filter is known as the G2 Filter, which stands for second  
 22 generation Recovery Filter. Bard later manufactured the G2 Express (also known as the G2X) and the  
 23 Eclipse filter, which are based on the Recovery Filter design. Once Bard and BPV had obtained FDA  
 24 approval to market the redesigned product in or around August 2005, Bard and BPV quietly stopped  
 25  
 26  
 27

1 marketing the Recovery Filter. Bard and BPV failed, however, to make any effort to notify consumers of  
 2 the risk inherent in the use of the Recovery Filter.  
 3  
 4

## 5 **THE G2 AND G2 EXPRESS FILTER SYSTEM**

6 38. In 2005, Bard and BPV redesigned its first-generation retrievable filter, Recovery Filter,  
 7 in an attempt to fix its design and manufacturing flaws. The redesigned filter is known as the G2 Filter,  
 8 which stands for second generation Recovery Filter.  
 9

10 39. On August 10, 2005, Bard and BPV submitted a Section 510(k) premarket notification of  
 11 intent to market the G2 Filter for the prevention of recurrent pulmonary embolism via permanent  
 12 placement in the inferior vena cava. Bard and BPV cited the Recovery Filter as the substantially  
 13 equivalent predicate device. Bard and BPV stated that the differences between the Recovery Filter and  
 14 the G2 Filter were primarily dimensional and no material changes or additional components were added.  
 15 On August 29, 2005, the FDA cleared the G2 Filter for the same intended uses as the Recovery Filter,  
 16 except that it was not cleared for retrievable use.<sup>4</sup>  
 17

18 40. Even after the redesigned G2 Filter was cleared for use, Bard and BPV failed to take any  
 19 steps to recall the Recovery Filter and/or to notify consumers that the failure rates associated with the  
 20 Recovery Filter were substantially higher than other similar products on the market.  
 21

22 41. Bard and BPV marketed the G2 Filter as having “enhanced fracture resistance,”  
 23 “improved centering,” and “increased migration resistance.” Despite these claims, however, Bard and  
 24 BPV failed to ensure that the changes made to the G2 Filter were sufficient to cure the defective and  
 25 unreasonably dangerous nature of the device. Thus, the G2 Filter shares the same defects and health  
 26 risks as its predicate device.  
 27

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28 <sup>4</sup> The FDA did not clear the G2® Filter to be used as a retrievable filter until January 15, 2008.

1       42. The G2 Filter's design causes it to be of insufficient integrity and strength to withstand  
 2 normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, and/or  
 3 perforating the inferior vena cava.  
 4

5       43. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from  
 6 manufacturing defects. These manufacturing defects include, but are not limited to, the existence of  
 7 "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The  
 8 presence of these draw markings and/or circumferential grinding markings further compromises the  
 9 structural integrity of the G2 Filter while *in vivo*. In particular, the G2 Filter is prone to fail at or near the  
 10 location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the  
 11 G2 Filter is not of sufficient strength to withstand normal placement within the human body. The  
 12 presence of the aforementioned exterior manufacturing defects makes the device more susceptible to  
 13 fatigue failure.  
 14

15       44. As with the Recovery Filter, Bard and BPV immediately began receiving large numbers  
 16 of AERs reporting that the G2 Filter was, *inter alia*, fracturing, migrating, and perforating the vena cava  
 17 once implanted. These failures were again often associated with reports of severe patient injuries such  
 18 as:  
 19

- 20       a. death;
- 21       b. hemorrhage;
- 22       c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the  
       area around the heart);
- 23       d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- 24       e. severe and persistent pain;
- 25       f. and perforations of tissue, vessels and organs.

26       45. Defendants represent the fracture rate of the G2 Filter to be 1.2%. Based upon a review of  
 27 the data available in the public domain (including the FDA MAUDE database statistics and the  
 28

1 published medical literature), this representation does not accurately reflect the true incidence of device  
 2 fracture for the G2 Filter.

3       46.     A review of the MAUDE database from the years 2004-2008 reveals data to establish that  
 4 the Bard and BPV's vena cava filters (including the G2 Filter) are responsible for the majority of all  
 5 reported adverse events related to inferior vena cava filters.

6       47.     The G2 Express filter was cleared by the FDA on July 30, 2008. The only significant  
 7 difference between this filter and the G2 was a new snare tip which was designed in an effort to  
 8 optimize retrieval. Bard launched and began marketing the G2 Express in August 2008. The G2 and the  
 9 G2 Express are the same filter, from a design standpoint, and share the same defects and complications.

10      48.     The G2X filter was cleared by the FDA on October 31, 2008. As with the G2® Express,  
 11 the G2X had minimal design difference between it and the G2 Filter. Bard launched the G2X Filter in  
 12 January 2009. The G2, G2 Express, and the G2X are the same filter, from a design standpoint, and share  
 13 the same defects and complications.

14      49.     Upon information and belief, Plaintiff alleges that as early as 2003, Bard and BPV were  
 15 aware and had knowledge of the fact that the Recovery Filter was defective and unreasonably dangerous  
 16 and was causing injury and death to patients who had received it. Similarly, Bard and BPV were aware  
 17 as early as 2005 that the G2 Filter System family was defective and unreasonably dangerous and was  
 18 causing injury and death to patients who had received it. And due to the similarities in design, Bard  
 19 should have known that the G2 Express and G2x were just as dangerous and defective.

20      50.     Data establishes that the failure rate of the G2 Filter System, and filters within that  
 21 family, was/is exceedingly higher than the rate that Bard and BPV have in the past, and currently  
 22 continue to publish to the medical community, members of the public. Further, Bard and BPV are aware  
 23 or should have been aware that the G2 Filter, the G2 Express, and the G2X have a substantially higher

failure rate than other similar products on the market, yet they have failed to warn consumers of this fact.

51. Upon information and belief, from the time the G2 Filter System became available on the market, the Defendants Bard and BPV embarked on an aggressive campaign of “off label marketing” concerning the G2 Filter System. These included representations made to physicians, healthcare professionals, and other members of the medical community that the G2 Filter System was safe and effective for retrievable use prior to the FDA approving the G2 Filter System for retrievable use.

52. Despite having knowledge as early as 2005 of the unreasonably dangerous and defective nature of the product, Bard and BPV consciously disregarded the known risks and continued to actively market and offer for sale the G2 Filter System and the G2® Express.

## THE ECLIPSE VENA CAVA FILTER

53. In an effort to resolve the complications associated with the G2 filter and the G2 Express, Bard designed the Eclipse Vena Cava Filter as the next generation in its filter family.

54. The Eclipse Filter was cleared by the FDA on January 14, 2010. The only design changes from the G2 family of filters to the Eclipse Filter was that hooks were added to the legs of the filter and the struts of the filter were electropolished. The Eclipse Filter continued to share several of the same design defects and complications associated with the Recovery Filter and G2 family of filters due to the fact that the Eclipse design was based on its predecessors.

55. Bard launched the Eclipse Filter in 2010. Soon thereafter, Bard began receiving similar complaints associated with the Eclipse filter as it had with the predecessor filters. For the reason that the Eclipse is based on Bard's previous filter designs, the Eclipse filter shares the same or similar design and manufacturing defects as Bard's previous filters and suffers from the same complications and defects.

## THE MERIDIAN FILTER

56. In August of 2011, the Meridian Filter was cleared by the F.D.A. for introduction to the global market. The Meridian Filter was also submitted under the notification provisions of section 510(k) of the United States Food, Drug and Cosmetic Act (“Act”) of 1976 (21 U.S.C. 321 *et seq.*). The Defendants represented to the F.D.A. that the Meridian was substantially similar to the Eclipse Filter System (predicate device).

57. The Meridian Filter system was the next generation of Bard's retrievable or optional filters. The Meridian Filter is made of the same nickel-titanium alloy, Nitinol, as the Bard Recovery, G2 and Eclipse Filters. The design of the Meridian is based on the Eclipse Filter System which is based entirely off the G2 filter which is also designed, manufactured and sold by the Defendants. Like the Eclipse, the Nitinol wires used in the Meridian Filter are electropolished prior to the forming of the filter.

58. As seen with the Recovery, G2 and Eclipse Filters, soon after its introduction to the market, reports were made that the Meridian Filters were fracturing, perforating, and/or migrating in the patients in which they were implanted. The Meridian Filter System was still plagued with manufacturing and design defects that were causing damage to the general public.

59. Upon information and belief, Plaintiff alleges that as early as 2011, Bard and BPV were aware and had knowledge of the fact that the Meridian Filter was defective and unreasonably dangerous and was causing injury to patients who had received it. Bard and BPV knew or should have known that the similarities in design between the Meridian Filter and its predecessors made the Meridian Filter just as dangerous and prone to defects and complications.

60. Data establishes that the failure rate of the Meridian Filter, and its predecessors, was/is exceedingly higher than the rate that Bard and BPV have in the past, and currently continue to publish to

1 the medical community, members of the public. Further, Bard and BPV are aware or should have been  
 2 aware that the Meridian Filter had a substantially higher failure rate than other similar products on the  
 3 market, yet they have failed to warn consumers of this fact.  
 4

5       61. Upon information and belief, from the time the Meridian Filter became available on the  
 6 market, the Defendants Bard and BPV embarked on an aggressive campaign of “off label marketing”  
 7 concerning the Meridian Filter. These included representations made to physicians, healthcare  
 8 professionals, and other members of the medical community that the Meridian Filter was safe and  
 9 effective for classes of patients when data and the Meridian Filter’s own clearance did not allow for such  
 10 representations.  
 11

12       62. Despite having knowledge as early as 2011, and even earlier based on predecessor filters,  
 13 of the unreasonably dangerous and defective nature of the product, Bard and BPV consciously  
 14 disregarded the known risks and continued to actively market and offer for sale the Meridian Filter.  
 15

16       63. The conduct of Bard and BPV as alleged in this Complaint constitutes willful, wanton,  
 17 gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of  
 18 Plaintiff and the community at large. Bard and BPV had actual knowledge of the dangers presented by  
 19 the Meridian Filter, yet consciously failed to act reasonably to:  
 20

- 21           a. Inform or warn Plaintiff, his physicians, or the public at large of these dangers;
- 22           b. Establish and maintain an adequate quality and post-market surveillance system;  
                  and
- 23           c. Recall the Meridian Filter System from the market.

24       64. Plaintiff further alleges that Bard and BPV acted in willful, wanton, gross and total  
 25 disregard for the health and safety of the users or consumers of their Meridian Filter, acted to serve their  
 26 own interests, and having reason to know and consciously disregarding the substantial risk that their  
 27 product might kill or significantly harm patients, or significantly injure the rights of others, consciously  
 28

pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

65. The failures of the Meridian Filter are attributable, in part, to the fact that the Meridian Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

## THE DENALI® FILTER

66. The Denali® filter was cleared by the FDA on May 15, 2013. It is Bard's latest generation device in the IVC filter product line.

67. Bard represented to the FDA that the Denali® was substantially similar to the Eclipse® filter, again bypassing formal pre-market FDA approval and instead utilizing the 510(k) process.

68. The Denali® Filter is also made of NITINOL. Its design is based on the Eclipse® filter, which in turn, was based on Bard's predecessor filter line. Like the Eclipse®, the NITINOL wires used in the Denali® filter are electropolished prior to the forming of the filter. The added features to the Denali® Filter were cranial and caudal anchoring systems (to reduce the prevalence of the filter migration) and penetration limiters.

69. However, as seen with the Recovery®, G2®, G2X® (G2 Express®), and Eclipse® Filters, soon after its introduction to the market, reports were made that the Denali® filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

70. The Denali® filter was likewise plagued with the same manufacturing and design defects that were causing damage to the general public in Bard's predecessor retrievable filter family.

1           71. At all times material hereto from the design phase, testing, and manufacture of the  
 2 Recovery® filter through the Denali® filter, Bard lacked a thorough understanding dynamics of  
 3 caval anatomy that impacted testing methods.  
 4

5           72. At this time, all Bard IVC Filters, Bard G2 IVC Filter, contain the same or  
 6 substantially similar defects resulting in the same or substantially similar mechanism of injury to  
 7 the Plaintiff.  
 8

9           73. At this time, all Bard IVC Filters, including the Bard G2 IVC Filter, are misbranded  
 10 and adulterated by virtue of them failing to be the substantial equivalent of their predecessor  
 11 devices, all of which were required to be as safe and effective as the original predicate device,  
 12 the Simon Nitinol Filter, and none were/are, making them subject to corrective action, including  
 13 recall, in the interest of patient safety. The use of each of these subject devices was  
 14 inappropriate and illegal since each was being marketed while adulterated and misbranded for  
 15 failing, among other things, to be as safe and effective as the originating predicate device, SNF.  
 16

17           74. At all relevant times, safer alternative designs existed for this product, including but  
 18 not limited to the Simon Nitinol filter, the ALN, the Gunther Tulip filter, and  
 19 modifications to the G2 filter, as well as reasonable treatment alternatives.  
 20

### **WHAT HAPPENS WHEN A BARD G2 ® FILTER SYSTEM FAILS?**

21           75. The failure (fracture, migration, and/or perforation) of the Bard G2® Filter System leads  
 22 to a number of different, and potentially fatal, complications. These complications include, but are not  
 23 limited to:  
 24

25

- 26           a. Death;
- 27           b. Hemorrhage;
- 28           c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area  
 29 around the heart);

- d. Severe and persistent pain; and
- e. Perforation of tissue, vessels and organs.

76. The person who experiences failure (fracture, migration, and/or perforation) of the Bard G2® Filter System typically experiences an acute onset of pain. This typically results in the person presenting to an emergency room, hospital, and/or physician for evaluation.

## THE CASE FOR MEDICAL MONITORING

77. In certain cases, medical monitoring is required to evaluate whether an Bard G2® Filter System (or portions of the Bard G2® Filter) has fractured, perforated and/or migrated (collectively referred to herein as “device failure” or “failure”). In order to determine whether failure of the Bard G2® Filter System has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT Scan) so that the filter may be visualized. CT Scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

78. Patients requiring medical monitoring are recommended<sup>5</sup> to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device, or portions of the device, remains within the body of the patient, the potential for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

79. Patients eligible for medical monitoring of the Bard G2® Filter System or portions of the device need not have experienced past failure of the Bard G2® Filter System. For example, patients who have undergone implant of the Bard G2® Filter System frequently learn that the Bard G2® Filter cannot

<sup>5</sup> Research studies performed in 2008 call for the need of regular and frequent medical monitoring for a patient who had the Recovery™ vena cava filter implanted in their body. This 2008 research study performed by Jeffrey Hull, M.D. recommends regular and frequent monitoring of patients in whom the Recovery Filter System remains implanted. (*Retrieval of the Recovery Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle*, Hull et. al., J. Vasc. Intern. Radiol.

1 be removed due to the fact that it has “grown into” tissue, but, the fracture, or migration of the device  
 2 may not yet have occurred. Other patients may experience fracture and migration of a piece of the filter  
 3 to other organs, such as the heart and lungs, where the risk of removal currently weighs against removal.  
 4 As a result of the inability to remove the Bard G2® Filter System, the device must remain permanently  
 5 implanted in the patient, for the patient’s lifetime. Although these patients may not yet have experienced  
 6 device failure, they are at risk for future device failure and require regular and frequent monitoring to  
 7 evaluate the integrity of the Bard G2® Filter System. In addition to the aforementioned imaging studies,  
 8 endovascular intervention (typically cardiac catheterization) may also be used by medical professionals  
 9 to diagnose or discover whether fractured portions of the Bard G2® Filter System have migrated to the  
 10 heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage  
 11 resulting from failure of the Bard G2® Filter System.

14       80.    In those instances where device fracture has occurred, and depending on the  
 15 circumstances particular to the patient, a person may be required to undergo one or all of the following  
 16 medical procedures:

18           a.    CT Scanning or other imaging studies;  
 19           b.    Cardiac Catheterization;  
 20           c.    Open heart surgery;  
 21           d.    Removal of the Bard G2 ® Filter System from the vena cava.

21       81.    The Bard G2® Filter System was placed in Plaintiff Ronald Alaniz body on or about  
 22 November 26, 2006. On or about March 27, 2019, it was discovered that all the Bard G2® Filter System  
 23 struts have penetrated and pierced through the IVC wall with one leg penetrating and embedded in the  
 24 L3 vertebral body.

28 2008; 19:1107.1111). Dr. Hull specifically recommends “imaging with un-enhanced abdominal CT to look for arm  
 29 perforation, fracture or migration to further evaluate the scope and risk posed by [the Recovery] filter.”

1       82.     As a direct and proximate result of the conduct and defective product of the Defendants  
 2 C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, Plaintiff Ronald Alaniz,  
 3 has suffered permanent and continuing injury, loss of enjoyment of life, pain, suffering, and impairment.  
 4 Plaintiff has suffered emotional trauma, harm and injuries. Plaintiff's ability to carry on the affairs of his  
 5 daily life has been impacted and diminished and will continue to diminish in the future.  
 6

7       83.     As a direct and proximate result of the conduct and defective product of the Defendants,  
 8 C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, the Plaintiff has  
 9 incurred substantial medical expenses, and will continue to incur substantial medical expenses into the  
 10 future.  
 11

### **THE NECESSITY FOR MEDICAL MONITORING**

13       84.     As a direct and proximate result of the conduct and defective product of the Defendants,  
 14 C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, medical monitoring is  
 15 necessary for Plaintiff's Medical monitoring includes:  
 16

- 17       a.     Regularly scheduled CT scans or other appropriate imaging studies; and/or
- 18       b.     Potential cardiac catheterization or other endovascular procedure to detect the  
 19 presence of migrated pieces of the Bard G2® Filter System and/or Physicians' visits and examinations.

### **THE DEFENDANTS'KNOWLEDGE OF THE FAILURE OF THE BARD G2® FILTER SYSTEM AND THE DANGERS ASSOCIATED WITH THE DEVICE**

22       85.     Upon information and belief, Plaintiff alleges that as early as 2003, the Defendants C.R.  
 23 Bard, Inc. and Bard Peripheral Vascular, Inc. were aware and had knowledge of the fact that the Bard  
 24 G2® Filter System was defective and unreasonably dangerous and was causing serious and potentially  
 25 life-threatening injuries to patients who had received the Bard G2® Filter System.  
 26

27       86.     From the time the Bard G2® Filter System became available on the market, the  
 28 Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., made representations to physicians,

1 healthcare professionals, and other members of the medical community that the Bard G2® Filter System  
2 was safe and effective for retrievable use, when they knew or should've known it wasn't.  
3

4 87. Data established that the failure rate of the Bard G2® Filter System was/is exceedingly  
5 higher than the rates the Defendants have published in the past, and currently continue to publish to the  
6 medical community, members of the public, and the F.D.A.  
7

8 88. Over 921 adverse events were identified by the F.D.A. through a warning issued in  
9 August of 2010 regarding the risks associated with IVC filter complications.  
10

11 89. The conduct of the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. as  
12 alleged in this Complaint, constituted, willful, wanton, gross, and outrageous corporate conduct that  
13 demonstrates a conscious disregard for the safety of the Plaintiff Ronald Alaniz. The Defendants C.R.  
14 Bard, Inc. and Bard Peripheral Vascular Inc. had actual knowledge of dangers to the life and limb of the  
15 Plaintiff Ronald Alaniz, presented by the Bard G2® Filter System, yet consciously failed to act  
16 reasonably to:  
17

- 18 a. Inform or warn the Plaintiff, his physicians, or the public at large of the dangers;  
19 and  
20 b. Recall the Bard G2® Filter System from the market in a timely and safe fashion;  
21

22 90. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective  
23 nature of the product, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. consciously  
24 disregarded the known risks and continued to actively market and offer for sale the Bard G2® Filter  
25 System. Plaintiff alleges that the Defendants acted in willful, wanton, gross manner, and in total  
26 disregard for the health and safety of the users or consumers of its Bard G2® Filter System, including  
27 Plaintiff Ronald Alaniz and acted to serve their own interests and having reason to know and  
28 consciously pursued a course of conduct knowing that such conduct created a substantial risk of  
29

1 significant harm to other persons. Therefore, Defendants should be required to respond to the Plaintiffs  
 2 in the form of a punitive or exemplary damage award.

3 **THE FEDERAL REQUIREMENTS**  
 4

5       91.    Federal regulation states that “recall means a firm’s removal or correction of a marketed  
 6 product that the Food and Drug Administration considers to be in violation of the laws it administers and  
 7 against which the agency would initiate legal action, e.g. seizure.” See 21 CFR §7.3(g).

8       92.    Federal regulation states that “recall classification means the numerical designation, i.e.,  
 9 I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the  
 10 relative degree of health hazard presented by the product being recalled.” See 21 CFR §7.3(m).

12       93.    Federal regulation states that “class II is a situation in which use of, or exposure to, a  
 13 violative product may cause temporary or medically reversible adverse health consequences or where  
 14 the probability of serious adverse health consequences is remote.” See 21 CFR §7.3(m).

15       94.    The classification of the product withdrawals and corrections of the Defendant’s devices  
 16 (described above) as Class II Recalls by the F.D.A confirms by definition that the devices were in  
 17 violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

19       95.    Pursuant to federal law, a device is deemed to be adulterated if, among other things, it  
 20 fails to meet established performance standards, or if the methods, facilities or controls used for its  
 21 manufacture, packing, storage or installation are not in conformity with federal requirements. See 21  
 22 U.S.C. §351.

24       96.    Pursuant to federal law, a device is deemed to be misbranded if, among other things, its  
 25 labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the  
 26 manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

1       97. Pursuant to federal law, manufacturers are required to comply with F.D.A. regulation of  
2 medical devices, including F.D.A. requirements for records and reports, in order to prohibit introduction  
3 of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of  
4 medical devices. In particular, manufacturers must keep records and make reports if any medical device  
5 that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a  
6 manner likely to cause or contribute to death or serious injury. Federal law also mandates that the F.D.A.  
7 establish regulations requiring a manufacturer of a medical device to report promptly to F.D.A. any  
8 correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy  
9 a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

12       98. Pursuant to federal law, the Secretary of Health and Human Services may prescribe  
13 regulations requiring that the methods used in, and that facilities and controls used for, the manufacture,  
14 pre-production design validation (including a process to assess the performance of a device but not  
15 including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of  
16 a device conform to current good manufacturing proactive, as prescribed in such regulations, to assure  
17 that the device will be safe and effective and otherwise in compliance with federal law. See 21. U.S.C  
18 §360j(f).

20       99. Pursuant to F.D.A. regulation, adverse events associated with a medical device must be  
21 reported to F.D.A. within 30 days after the manufacturer becomes aware that a device may have caused  
22 or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause  
23 or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all  
24 information reasonably known to the manufacturer, including any information that can be obtained by  
25 analysis, testing, or other evaluation of the device, and any information in the manufacturer's  
26  
27

1 possession. In addition, manufacturers are responsible for conducting an investigation of each adverse  
2 event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

3       100. Pursuant to federal regulation, manufacturers of medical devices must also describe in  
4 every individual adverse event report whether remedial action was taken in regard to the adverse event,  
5 and whether the remedial action was reported to F.D.A. as a removal or correction of the device. See 21  
6 CFR §803.52.

7       101. Pursuant to federal regulation, manufacturers must report to F.D.A. within five (5)  
8 business days after becoming aware of any reportable MDR event or events, including a trend analysis  
9 that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.  
10 See 21 CFR §803.53.

11       102. Pursuant to federal regulation, device manufacturers must report promptly to F.D.A. any  
12 device corrections and removals and maintain records of device corrections and removals. F.D.A.  
13 regulations require submission of a written report within ten (10) working days of any correction or  
14 removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to  
15 remedy a violation of the Act caused by the device, which may present a risk to health. The written  
16 submission must contain, among other things, a description of the event giving rise to the information  
17 reported and the corrective or removal actions taken, and any illness or injuries that have occurred with  
18 use of the device, including reference to any device report numbers. Manufacturers must also indicate  
19 the total number of devices manufactured or distributed which are subject to the correction or removal,  
20 and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

21       103. Pursuant to federal regulation, manufacturers must comply with specific quality system  
22 requirements promulgated by F.D.A. These regulations require manufacturers to meet design control  
23 requirements, including but not limited to conducting design validation to ensure that devices conform

1 to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture  
2 and production. Manufacturers must establish and maintain procedures for implementing corrective  
3 actions and preventive actions and investigate the cause of nonconforming products and take corrective  
4 action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and  
5 determine whether an investigation is necessary. Manufacturers are also required to use statistical  
6 techniques where necessary to evaluate product performance. See 21 CFR §820.

8 104. The regulations requiring conformance to good manufacturing practices are set forth in  
9 21 CFR §820 et seq. As explained in the Federal Register, because the Current Good Manufacturing  
10 Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe  
11 the details for how a manufacturer must produce a device. Rather, the quality system regulations provide  
12 a framework of basic requirements for each manufacturer to use in establishing a quality system  
13 appropriate to the devices designed and manufactured, and the manufacturing processes employed.  
14 Manufacturers must adopt current and effective methods and procedures for each device they design and  
15 manufacture to comply with and implement the basic requirements set forth in the quality system  
16 regulations.

19 105. Pursuant to 21 CFR §820.1(c), the failure to comply with any applicable provision in Part  
20 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act (“the  
21 Act”) (21 U.S.C. § 351).

23 106. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality  
24 system that is appropriate for the specific medical device designed or manufactured. “Quality system”  
25 means the organizations structure, responsibilities, procedures, processes, and resources for  
26 implementing quality management. See 21 CFR §820.3(v).

1       107. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality  
2 audits and conduct such audits to assure that the quality system is in compliance with the established  
3 quality system requirements and to determine the effectiveness of the quality system.  
4

5       108. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain  
6 procedures to control the design of the device in order to ensure that specified design requirements are  
7 met.  
8

9       109. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain  
10 procedures for defining and documenting design output in terms that allow an adequate evaluation of  
11 conformance to design input requirements.  
12

13       110. Pursuant to 21 CFR §820.30(e), each manufacturer shall establish and maintain  
14 procedures to ensure that formal documented reviews of the design results are planned and conducted at  
15 appropriate stages of the device's design development.  
16

17       111. Pursuant to 21 CFR §820.30(f), each manufacturer shall establish and maintain  
18 procedures for verifying the device design to confirm that the device design output meets the design  
19 input requirements.  
20

21       112. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain  
22 procedures for validating the device design. Design validation shall be performed under defined  
23 operating conditions on initial production units, lots, or batches, or their equivalents. Design validations  
24 shall ensure that devices conform to defined user needs and intended uses and shall include testing of  
25 production units under actual or simulated use conditions.  
26

27       113. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain  
28 procedures to ensure that the device design is correctly translated into production specifications.  
29

1       114. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain  
 2 procedures for the identification, documentation, validation or where appropriate verification, review,  
 3 and approval of design changes before their implementation.  
 4

5       115. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and  
 6 monitor production processes to ensure that a device conforms to its specifications. Where deviations  
 7 from device specifications could occur as a result of the manufacturing process, the manufacturer shall  
 8 establish and maintain process control procedures that describe any process controls necessary to ensure  
 9 conformance to specifications. Such process controls shall include:

- 11       a. Documented instructions, standard operating procedures (SOP's), and methods  
       that define and control the manner of production;
- 12       b. Monitoring and control of process parameters and component and device  
       characteristics during production;
- 13       c. Compliance with specified reference standards or codes;
- 14       d. The approval of processes and process equipment; and
- 15       e. Criteria for workmanship which shall be expressed in documented standards or by  
       means of identified and approved representative sample.

16       116. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain  
 17 procedures for changes to a specification, method, process, or procedure.  
 18

19       117. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain  
 20 procedures to adequately control environmental conditions that could reasonably be expected to have an  
 21 adverse effect on product quality, including periodic inspection of environmental control system(s) to  
 22 verify that the system, including necessary equipment, is adequate and functioning properly.  
 23

24       118. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain  
 25 procedures to prevent contamination of equipment or product by substances that could reasonably be  
 26 expected to have an adverse effect on product quality.  
 27

1       119. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used  
2 in the manufacturing process meets specified requirement and is appropriately designed, constructed,  
3 placed, and installed to facilitate maintenance, adjustment, cleaning and use.

4       120. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain  
5 procedures for the use and removal of manufacturing material which could reasonably be expected to  
6 have an adverse effect on product quality to ensure that it is removed or limited to an amount that does  
7 not adversely effect the device's quality.

8       121. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems  
9 are used as part of production or the quality system, the manufacturer shall validate computer software  
10 for its intended use according to an established protocol.

11       122. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection,  
12 measuring, and test equipment, including mechanical, automated, or electronic inspection and test  
13 equipment, is suitable for its intended purposes and is capable of producing valid results. Each  
14 manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated,  
15 inspected, checked, and maintained.

16       123. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by  
17 subsequent inspection and test, the process shall be validated with a high degree of assurance and  
18 approved according to established procedures. "Process validation" means establishing by objective  
19 evidence that a process consistently produces a result or product meeting its predetermined  
20 specifications. See 21 CFR §820.3(z)(1).

21       124. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain  
22 procedures for monitoring and control of process parameters for validated processes to ensure that the  
23

1 specified requirements continue to be met. Each manufacturer shall ensure that validated processes are  
 2 performed by qualified individuals.

3 125. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures  
 4 to control product that does not conform to specified requirements.  
 5

6 126. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures  
 7 for implementing corrective and preventive action. The procedures shall include requirements for:  
 8

- 9 a. Analyzing processes, work operations, concessions, quality audit reports, quality  
 10 records, service records, complaints, returned product, and other sources of  
 quality data to identify existing and potential causes of nonconforming product, or  
 other quality problem,
- 11 b. Investigating the cause of nonconformities relating to product, processes and the  
 12 quality system;
- 13 c. Identifying the action(s) needed to correct and prevent recurrence of  
 14 nonconforming product and other quality problems;
- 15 d. Verifying or validating the corrective and preventative action to ensure that such  
 16 action is effective and does not adversely affect the finished device;
- 17 e. Implementing and recording changes in methods and procedures needed to correct  
 18 and prevent identified quality problems;
- 19 f. Ensuring that information related to quality problems or nonconforming product  
 20 is disseminated to those directly responsible for assuring the quality of such  
 21 product or the prevention of such problems; and
- 22 g. Submitting relevant information on identified quality problems, as well as  
 23 corrective and preventative actions, for management review.

24 **DEFENDANTS' BARD G2® FILTER SYSTEM IS A 510(k) CLEARED**  
 25 **MEDICAL DEVICE**

26 127. Defendants submitted a §510(k) premarket notification and obtained marketing clearance  
 27 for its Bard G2® Filter System from the F.D.A. under Section 510(k) of the Act. *See* 21 U.S.C. §360 *et*  
 28 *seq.*

128. Under the §510(k) approval process, the F.D.A. determined that Defendants' Bard G2®

Filter System was “substantially equivalent” to devices that have been reclassified in accordance with the provisions of the Act and did not require F.D.A. approval of a pre-market approval application (PMA).

129. Upon information and belief, Defendants' Bard G2® Filter System is adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

130. Upon information and belief, Defendants' Bard G2® Filter System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

131. Upon information and belief, Defendants' Bard G2® Filter System is adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their Bard G2® Filter System in accordance with 21 CFR §820 *et seq.*, as set forth above.

132. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their Bard G2® Filter System.

133. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Bard G2® Filter System was defective and failed, resulting in injuries to the Plaintiff.

134. If Defendants had complied with the federal requirements regarding CGMP, Defendants' Bard G2® Filter System would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

## **SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF**

135. On or about November 26, 2006, Plaintiff Ronald Alaniz underwent surgical placement of a Bard G2® Filter System.

136. This Bard G2® Filter System was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants Bard and BPV.

137. On or about March 27, 2019 it was discovered that all the Bard G2® Filter System struts have penetrated and pierced through the IVC wall with one leg penetrating and embedded in the L3 vertebral body. The filter system caused serious injury to the Plaintiff and presented a risk of serious injury and/or death in the future. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, and other losses, some of which are permanent in nature. As a result of the failure of the Bard G2® Filter System, Plaintiff has become impaired and his ability to earn wages has been diminished and will remain so in the future. Plaintiff still experiences the physical and mental sequalae suffered as a result of the filter and the injuries caused.

## **FRAUDULENT CONCEALMENT**

138. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

139. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery®, G2®, Eclipse ® and Meridian ® Filter Systems.

140. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

## **CORPORATE/VICARIOUS LIABILITY**

141. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

142. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

143. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

144. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

## **FIRST CAUSE OF ACTION NEGLIGENCE**

145. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

146. At all times relevant to this cause of action, the Defendants Bard and BPV were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Bard G2® Filter System.

147. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Bard G2® Filter System that was implanted in Plaintiff.

148. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Bard G2® Filter System so as to avoid exposing others to foreseeable and unreasonable risks of harm.

149. Defendants knew or reasonably should have known that the Bard G2® Filter System was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

150. At the time of manufacture and sale of the Bard G2® Filter System Defendants knew or  
should have known that the Bard G2® Filter System:

- a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
- b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or
- c. Was designed and manufactured so as to present a unreasonable risk of the device perforating the vena cava wall; and/or
- d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

151. At the time of manufacture and sale of the Bard G2® Filter System, Defendants knew or should have known that using the filter in its intended use or in a reasonably foreseeable manner created

1 a significant risk of a patient suffering severe health side effects, including, but not limited to:  
 2 hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to  
 3 myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and  
 4 diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental  
 5 anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment  
 6 due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring  
 7 additional medical and surgical procedures including general anesthesia, with attendant risk of life  
 8 threatening complications.

10  
 11 152. Defendants knew or reasonably should have known that consumers or users of the Bard  
 12 G2® Filter System would not realize the danger associated with using the device in its intended use  
 13 and/or in a reasonably foreseeable manner.

14  
 15 153. Defendants breached their duty to exercise reasonable and prudent care in the  
 16 development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and  
 17 sale of the Bard G2® Filter System in, among other ways, the following acts and omissions:

- 18 a. Designing and distributing a product in which they knew or should have known that  
     19 the likelihood and severity of potential harm from the product exceeded the burden of  
     taking safety measures to reduce or avoid harm;
- 20 b. Failing to use reasonable care in manufacturing the product and producing a product  
     21 that differed from their design or specifications or from other typical units from the  
     same production line;
- 22 c. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's physicians, or  
     23 the general health care community about the Bard G2 ® Filter's substantially  
     24 dangerous condition or about facts making the product likely to be dangerous;
- 25 d. Failing to perform reasonable pre and post-market testing of the Bard G2 ® Filter  
     26 System to determine whether or not the product was safe for its intended use;
- 27 e. Failing to provide adequate instructions, guidelines, and safety precautions to those  
     28 persons to whom it was reasonably foreseeable would prescribe, use, and implant the  
     Bard G2 ® Filter System;

- f. Advertising, marketing and recommending the use of the Bard G2 ® Filter System, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the Bard G2 ® Filter System;
- g. Representing that the Bard G2 ® Filter System was safe for its intended use when in fact, the Defendants knew and should have known the product was not safe for its intended purpose;
- h. Continuing manufacture and sale of the Bard G2 ® Filter System with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA regulations and policy;
- i. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Bard G2 ® Filter System so as to avoid the risk of serious harm associated with the use of the G2 ® Filter;
- j. Advertising, marketing, promoting and selling the Bard G2 ® Filter System for uses other than as approved and indicated in the product's label;
- k. Failing to establish an adequate quality assurance program used in the manufacturing of the Bard G2 ® Filter System;
- l. Failing to establish and maintain and adequate post-market surveillance program. Failing to establish and maintain and adequate post-market surveillance program.

154. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

155. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

**SECOND CAUSE OF ACTION  
STRICT PRODUCTS LIABILITY - FAILURE TO WARN**

156. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

1       157. Defendants designed, set specifications, manufactured, prepared, compounded,  
2 assembled, processed, marketed, labeled, distributed, and sold the Bard G2 ® Filter System, including  
3 the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly  
4 advertised and marketed the device to consumers or persons responsible for consumers, and therefore  
5 had a duty to warn of risk of harm associated with the use of the device and to provide adequate  
6 instructions on the safe and proper use of the device.

8       158. At the time Defendants designed, manufactured, prepared, compounded, assembled,  
9 processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants  
10 knew or should have known the device was defective and presented an unreasonable danger to users of  
11 the product when put to its intended and reasonably anticipated use. The Defendants failed to adequately  
12 warn of the device's known or reasonably scientifically knowable dangerous propensities, and failed to  
13 provide adequate instructions on the safe and proper use of the device.

15       159. The Defendants knew or should have known at the time they manufactured, labeled,  
16 distributed and sold the Bard G2 ® Filter System, which was implanted in Plaintiff, that the Bard G2 ®  
17 Filter System, *inter alia*, posed a significant and higher risk than other similar devices of device failure  
18 (fracture, migration, and perforation of the vena cava wall) and resulting serious injuries.

20       160. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of  
21 the device and to provide adequate instructions on the safe and proper use of the device. Defendants  
22 further had a duty to warn of dangers and proper safety instructions that it became aware of even after  
23 the device was distributed and implanted in Plaintiff.

25       161. The Defendants failed to timely and reasonable warn of material facts regarding the  
26 safety and efficacy of the Bard G2 ® Filter System. No health care provider, including Plaintiff's  
27

1 physicians, or patient would have used the device in the manner directed, had those facts been made  
2 known to the prescribing healthcare providers and/or ultimate users of the device.

3 162. The warnings, labels, and instructions provided by the Defendants at all times relevant to  
4 this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the  
5 risks and benefits and lack of safety and efficacy associated with the device.

6 163. The Defendants failed to perform, establish or otherwise facilitate adequate testing and/or  
7 quality assurance programs; either of which would have shown that the device posed serious and  
8 potential life threatening adverse effects and complications.

9 164. The health risks associated with the device as described herein are of such a nature that  
10 ordinary consumers would not have readily recognized the potential harm. The device, which was  
11 designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed,  
12 and sold into the stream of commerce by the Defendants, was defective at the time of release into the  
13 stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

14 165. When Plaintiff was implanted with the device, the Defendants failed to provide any  
15 warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as  
16 discussed herein.

17 166. Neither Plaintiff nor the health care providers knew of the substantial danger associated  
18 with the intended and foreseeable use of the device as described herein until after Plaintiff's injury.

19 167. Plaintiff and Plaintiff's health care providers used the device in a normal, customary,  
20 intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary  
21 embolisms.

1       168. Upon information and belief, the Bard G2 ® Filter System implanted in Plaintiff was  
 2 defective and unreasonably dangerous at the time of release into the stream of commerce due to  
 3 inadequate warnings, labeling and/or instructions accompanying the product.  
 4

5       169. The Bard G2 X® Filter System implanted in Plaintiff was in the same condition as when  
 6 it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.  
 7

8       170. As a direct and proximate result of Defendants' lack of sufficient warning and/or  
 9 instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss,  
 10 loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.  
 11

**THIRD CAUSE OF ACTION**  
**STRICT PRODUCTS LIABILITY – DESIGN DEFECTS**

12       171. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
 13 the foregoing paragraphs as though fully set forth herein.  
 14

15       172. At all times relevant to this action, Defendants developed, tested, designed,  
 16 manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Bard  
 17 G2 ® Filter System, including the one implanted in Plaintiff.  
 18

19       173. The Bard G2 ® Filter System was expected to, and did, reach its intended consumers  
 20 without substantial change in the condition in which it was in when it left Defendants' possession. In the  
 21 alternative, any changes that were made to Bard G2 ® Filter System implanted in Plaintiff were  
 22 reasonably foreseeable to Defendants.  
 23

24       174. The Bard G2 ® Filter System implanted in Plaintiff was defective in design because it  
 25 failed to perform as safely as persons who ordinarily use the product would have expected at the time of  
 26 use.  
 27

28       175. The Bard G2 ® Filter System implanted in Plaintiff was defective in design, in that its  
 29 risks of harm exceeded its claimed benefits.  
 30

176. Plaintiff and Plaintiff's health care providers used the Bard G2 ® Filter System in a manner that was reasonably foreseeable to Defendants.

177. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

178. As a direct and proximate result of the Bard G2 ® Filter System's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

**FOURTH CAUSE OF ACTION  
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

179. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

180. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Bard G2 ® Filter System that was implanted into Plaintiff.

181. The Bard G2 ® Filter System implanted in Plaintiff contained a manufacturing defect when it left the Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical units of the same product line.

182. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

183. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

184. As a direct and proximate result of the Bard G2 ® Filter System's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

**FIFTH CAUSE OF ACTION  
BREACH OF EXPRESS WARRANTY**

185. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

186. The Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Bard G2 ® Filter was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

187. At the time of making such express warranties, the Defendants knew and/or should have known that the Bard G2 ® Filter System did not conform to the express warranties and representations and that, in fact, the Bard G2 ® Filter System is not safe and poses serious health risks, of which the Defendants did not accurately warn.

188. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe personal injuries and economic loss.

189. Plaintiff, his health care providers, and other consumers relied on the express warranties made by the Defendants regarding the safety and efficacy of the Bard G2 ® Filter System and were reasonable in doing so.

190. The Defendants inclusive, and each of them, breached their express warranties because the Bard G2 ® Filter System was and continues to be defective and not reasonably safe for its intended purpose.

191. The Defendants expressly represented and warranted to the medical community and American consumers, including Plaintiff and his healthcare providers that the Bard G2 ® Filter System was safe and fit for the purposes intended, that it was of merchantable quality, that it did not pose dangerous health risks in excess of those risks associated with use of other similar devices, that the side effects it did produce were accurately reflected in the warnings, and that it was adequately tested and fit for its intended use.

192. The Defendants knew and should have known that the representations and express warranties were false, misleading, and untrue in that said Defendants knew the Bard G2 ® Filter System was not safe and fit for its intended use, and that the Bard G2 ® Filter System caused its users serious injuries that were not adequately warned of, identified, or represented by these Defendants.

193. As a foreseeable, direct and proximate result of the Defendants breaching their express warranties, as described herein, Plaintiff has suffered injuries as described herein.

**SIXTH CAUSE OF ACTION  
BREACH OF IMPLIED WARRANTY**

194. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

195. At all times relevant to this action, the Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Bard G2 ® Filter System for use as a temporary surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

196. At the time and place of the sale, distribution, and supply of the Defendants' Bard G2 ® Filter System to Plaintiff by way of his health care providers and medical facilities, the Defendants

1 expressly represented and warranted, by labeling materials submitted with the product, that the Bard G2  
 2 ® Filter System was safe and effective for its intended use.

3       197. The Defendants knew of the intended use of the Bard G2 ® Filter System, at the time  
 4 they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product  
 5 to be of merchantable quality, and safe and fit for its intended use.

6       198. The Defendants impliedly represented and warranted to the healthcare community,  
 7 Plaintiff and his health care providers, that the Bard G2 ® Filter System was safe and of merchantable  
 8 quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

9       199. The representations and implied warranties made by the Defendants were false,  
 10 misleading, and inaccurate because the Bard G2 ® Filter System was defective, unsafe, unreasonably  
 11 dangerous, and not of merchantable quality, when used as it was marketed and intended to be used.  
 12 Specifically, at the time Plaintiff purchased the Bard G2 ® Filter System from the Defendants, through  
 13 his attending physicians and medical facilities, it was not in a merchantable condition in that:

- 14           a. It was designed in such a manner so as to be prone to a statistically high incidence of  
 15 failure, including fracture, migration, and perforation of the inferior vena cava; and
- 16           b. It was designed in such a manner so as to result in a statistically significant incidence  
 17 of injury to the organs and anatomy.

18       200. Plaintiff and the health care providers reasonably relied on the superior skill and  
 19 judgment of the Defendants as the designers, researchers and manufacturers of the product, as to  
 20 whether the Bard G2® Filter was of merchantable quality and safe and fit for its intended use, and also  
 21 relied on the implied warranty of merchantability and fitness for the particular use and purpose for  
 22 which the Bard G2® Filter was manufactured and sold.

23       201. The Defendants placed the Bard G2 ® Filter System into the stream of commerce in a  
 24 defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach

Plaintiff without substantial change in the condition in which the Bard G2 ® Filter System was manufactured and sold.

202. The Defendants breached their implied warranty because their Bard G2 ® Filter System was not fit for its intended use and purpose.

203. As a proximate result of the Defendants breaching their implied warranties, Plaintiff was caused to suffer the injuries and damages described in this complaint.

**SEVENTH CAUSE OF ACTION  
FRAUDULENT MISREPRESENTATION**

204. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

205. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of the Bard G2 ® Filter System, owed a duty not to deceive Plaintiff, his health care providers and the public regarding the character, safety, quality and/or effectiveness of their product.

206. Since the product's approval and on multiple occasions to the present date, Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality and effectiveness.

207. At the time of Defendants' fraudulent misrepresentations, Plaintiff was unaware of the falsity of the statements and reasonably believed them to be true.

208. Defendants breached their duties to Plaintiff by providing false, incomplete, and misleading information regarding Bard G2 ® Filter System.

209. Defendants acted with deliberate intent to deceive and mislead Plaintiff, the medical providers, and the public.

210. Plaintiff reasonably relied on Defendants' deceptive, inaccurate and fraudulent misrepresentations.

211. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses.

212. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

**EIGHT CAUSE OF ACTION  
NEGLIGENCE MISREPRESENTATION**

213. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

214. At all times relevant to this cause, and as detailed *supra*, the Defendants negligently provided Plaintiff, the public at large, and the medical community, with false or incorrect information, or omitted or failed to disclose material information concerning the Bard G2® Filter System, including, but not limited to, misrepresentations relating to the following subject areas:

- a. The safety of the Bard G2® Filter System;
- b. The efficacy of the Bard G2® Filter System;
- c. The rate of failure of the Bard G2® Filter System; and
- d. The approved uses of the Bard G2® Filter System.

215. The information distributed by the Defendants to the public, the medical community and Plaintiff was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and

1 misleading, and contained omissions and concealment of the truth about the dangers of the use of the  
2 Bard G2 ® Filter System. The Defendants made the foregoing misrepresentations knowing that they  
3 were false or without reasonable basis. These materials included instructions for use and warning  
4 document that was included in the package of the Bard G2 ® Filter System that was implanted in  
5 Plaintiff.

7 216. The Defendants' intent and purpose in making these misrepresentations was to deceive  
8 and defraud the public and the medical community, including Plaintiff's healthcare providers; to gain  
9 the confidence of the public and the medical community, including Plaintiff's healthcare providers; to  
10 falsely assure them of the quality of the Bard G2 ® Filter System and its fitness for use; and to induce  
11 the public and the medical community, including Plaintiff's healthcare providers to request, recommend,  
12 prescribe, implant, purchase, and continue to use the Bard G2 ® Filter System.

14 217. The foregoing representations and omissions by the Defendants were in fact false. The  
15 Bard G2 ® Filter System is not safe, fit, and effective for human use in its intended and reasonably  
16 foreseeable manner. The use of the Bard G2 ® Filter System is hazardous to the user's health, and said  
17 device has a serious propensity to cause users to suffer serious injuries, including without limitation, the  
18 injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do  
19 other comparable devices.

21 218. In reliance upon the false and negligent misrepresentations and omissions made by the  
22 Defendants, Plaintiff and his health care providers were induced to, and did use the Bard G2 ® Filter  
23 System, thereby causing Plaintiff to sustain severe and permanent personal injuries. The Defendants  
24 knew and had reason to know that Plaintiff, his health care providers, and the general medical  
25 community did not have the ability to determine the true facts intentionally and/or negligently concealed  
26  
27

1 and misrepresented by the Defendants, and would not have prescribed and implanted same, if the true  
2 facts regarding the device had not been concealed and misrepresented by the Defendants.

3 219. The Defendants had sole access to material facts concerning the defective nature of the  
4 product and its propensity to cause serious and dangerous complications in the form of dangerous  
5 injuries and damages to persons who are implanted with the Bard G2 ® Filter System.

6 220. At the time the Defendants failed to disclose and misrepresented the foregoing facts, and  
7 at the time Plaintiff used the Bard G2 ® Filter System, Plaintiff and his health care providers were  
8 unaware of said Defendants' negligent misrepresentations and omissions.

9 221. Plaintiff, his health care providers and the general medical community reasonably relied  
10 upon the misrepresentations and omissions made by the Defendants where knowledge of the concealed  
11 and misrepresented facts were critical to understanding the true dangers inherent in the use of the Bard  
12 G2 ® Filter System.

13 222. Plaintiff and his health care provider's reliance on the foregoing misrepresentations and  
14 omissions by the Defendants was the direct and proximate cause of Plaintiff's harm as described herein.

#### **PUNITIVE DAMAGES ALLEGATIONS**

15 223. Plaintiff incorporates by reference each preceding and succeeding paragraph as though  
16 set forth fully at length herein.

17 224. Plaintiffs' injury was the result of misconduct of Defendants that manifested a flagrant  
18 disregard of the safety of persons who might be harmed by the product in question.

19 225. Defendants fraudulently withheld information known to be material and relevant to the  
20 harm that Plaintiffs suffered or misrepresented the information of that type.

1       226. Defendants engaged in fraudulent and malicious conduct towards Plaintiff, his medical  
 2 providers and the public, and thereby acted with willful and wanton and/or conscious and reckless  
 3 disregard for the safety of Plaintiff and the public.

4       227. Defendants are liable to Plaintiffs for punitive damages for their wanton, reckless and/or  
 5 willful conduct in the manufacturing, designing, formulating, producing, creating, making, constructing,  
 6 and/or assembling a product that is defective.

7       228. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each  
 8 allegation into this Count, as if set forth at length, in its entirety.

9       229. Plaintiff is entitled to an award of punitive and exemplary damages based upon  
 10 Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their  
 11 complete and total reckless disregard for the public safety and welfare.

12       230. Defendants had knowledge of, and were in possession of evidence demonstrating that, the  
 13 G2 ® Filter was defective and unreasonably dangerous and had a substantially higher failure rate than  
 14 did other similar devices on the market. Yet, Defendants failed to:

- 15           a. Inform or warn Plaintiff or the health care providers of the dangers;
- 16           b. To establish and maintain an adequate quality and post-market surveillance system;  
 17           and
- 18           c. Recall the Bard G2® Filter System from the market.

19       231. Defendants acted to serve their own interests and having reasons to know and  
 20 consciously disregarding the substantial risk that their product might kill or significantly harm patients,  
 21 or significantly injure the rights of others, and consciously pursued a course of conduct knowing that  
 22 such conduct created a substantial risk of significant harm to other persons.

23       232. As a direct, proximate, and legal result of Defendants' acts and omissions a described  
 24 herein, and Plaintiff implantation with Defendants' defective product, Plaintiff has suffered and will

1 continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other  
2 losses, in an amount to be determined at trial.

3 **PRAAYER FOR DAMAGES**

4 **WHEREFORE**, Plaintiff, prays for relief on the entire complaint, as follows:

5 a. Judgment to be entered against all defendants on all causes of action of this  
6 Complaint, including but not limited to:

7 1. Physical pain and suffering in the past and which, in reasonable  
8 probability, he will continue to suffer in the future;

9 2. Physical impairment and incapacity in the past and which, in reasonable  
10 probability, he will continue to suffer in the future;

11 3. Pain, suffering and mental anguish in the past and which, in reasonable  
12 probability, he will sustain in the future;

13 4. Reasonable and necessary medical expenses for treatment received in the  
14 past and, based upon reasonable medical probability, the reasonable  
15 medical expenses he will need in the future;

16 5. Loss of earning capacity in the past and future; and

17 6. Punitive damages.

18 b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of  
19 action relevant to this action;

20 c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and  
21 post judgment interest pursuant to the laws of the State of Texas as authorized by  
22 law on the judgments entered in Plaintiffs' behalf; and,

23 d. Such other relief the court deems just and proper.

24 **DEMAND FOR JURY TRIAL**

25 Plaintiff hereby demands trial by jury on all issues.

1                   Dated: March 26<sup>th</sup>, 2021

Respectfully Submitted,

2                   **MARTIN | BAUGHMAN, PLLC**

3                   */s/ Kristi Wood*

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